



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,278	07/31/2001	Herm Snyder	0068.00	4703

21968 7590 01/13/2003

INHALE THERAPEUTIC SYSTEMS, INC
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,278

Applicant(s)

SNYDER ET AL

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment A and the Election, both received by the Office on October 28, 2002.

Status of Claims

Applicant has canceled claims 1-18 and elected claims 19-31 without traverse. This election is hereby made final.

Information Disclosure Statement

The information disclosure statement filed August 19, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-23, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the language "feed stock." It is confusing to the examiner what is meant by this terminology. Feed stock is generally accepted to mean something that can be

Art Unit: 1615

administered orally. However, in this case applicant is making particles for pulmonary administration. Clarification is respectfully requested.

Claims 20-23 recite sizes according to ranges, however, there is no indication of an actual diameter as a starting point for the range. As stated the language offers no further limitation to the claim. It is recommended that applicant insert an actual diameter into each of these claims.

Claim 31 is objected to as containing abbreviations. Appropriate clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19-24, and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,305,210 to Christensen *et al.*. Christensen *et al.* describe an apparatus for processing a product by forming a vibrating fluidized bed supported by a thin, perforated bedplate which is vibrated while gas is blown upwardly through the perforations of the plate. More specifically, Christensen *et al.* teach a plate comprising a multiplicity of closely spaced punched small openings, a product feeding means for feeding a product onto said plate, vibrating means for vibrating said plate, gas supply means for supplying a flow of gas, and product discharge means for discharging said product from the apparatus.

Art Unit: 1615

Christensen *et al.* do not specify a particular particle size for the resulting product. However, it is again noted that applicant's claims 19-25 do not require a particular particle size. Furthermore, it is the position of the examiner that, absent evidence to the contrary, the determination of a particular particle size is within the skill of the ordinary worker as part of the process of normal optimization.

Additionally, Christensen *et al.* do not specify that the particles are porous. However, it is the position of the examiner that such a limitation does not impart patentable distinction to the claims, because porosity depends on the substances being used in the process, and this is not defined by applicant. Furthermore, there is no evidence that the resulting product of Christensen is not porous.

It is the position of the examiner that the broad teachings of Christensen *et al.* suggest the limitations of applicant's broad claims. One of ordinary skill in the art would have been motivated to create a fluidized batch of particles using an apparatus involving a vibratable plate and a spray drying means comprising a gas. The expected result would be a processed product which is dryer than a typical product. Therefore this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Christensen *et al.*, as applied to claim 1-24 and 26-31 above, and further in view of JP 408015955 to Noda *et al.*. Christensen *et al.* teach that their apparatus contains a vibrating means, but they do not specify what that vibrating means is. Noda *et al.* are relied upon for the teaching that coupling a piezoelectric element to a vibratable surface can result in the vibration of that surface. Therefore,

Art Unit: 1615

Noda *et al.* are relied upon to teach piezoelectric elements as vibrating means. It is the position of the examiner that one of ordinary skill in the art would have been motivated to use any type of vibrating means, including a piezoelectric elements, as taught by Noda *et al.*, as the vibrating means discussed by Christensen *et al.*. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner/ AU 1615
January 13, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600